## Claims:

- 1. Use of an IFN-β therapeutic in the manufacture of a medicament for the treatment or prevention of glomerulonephritis in a mammal.
- The use of claim 1, wherein glomerulonephritis is selected from the group
   consisting of focal glomeruloscerosis, collapsing glomerulopathies, minimal change disease, crescentic glomerulonephritis, nephritic syndrome, nephrotic syndrome, primary glomerulonephritis, secondary glomerulonephritis, proliferative glomerulonephritis, membraneous glomerulonephritis, membranoproliferative glomerulonephritis, immune-complex glomerulonephritis, anti-glomerular basement membrane (anti-GBM) glomerulonephritis, pauci-immune glomerulonephritis, diabetic glomerulopathy, chronic glomerulonephritis, and hereditary nephritis.
  - 3. The use of claim 1 or 2, wherein the IFN-β therapeutic comprises mature IFN-β.
  - 4. The use of any one of claims 1-3, wherein the IFN- $\beta$  therapeutic lacks the first methione.
- 15 5. The use of any one of claims 1-4, wherein the IFN-β is human IFN-β.
  - 6. The use of claim 5, wherein the IFN-β is at least about 95% identical to full length mature human IFN-β having SEQ ID NO: 4.
  - 7. The use of claim 6, wherein the IFN-β comprises SEQ ID NO: 4.
  - 8. The use of any one of claims 1-7, wherein the IFN- $\beta$  is glycosylated.
- 20 9. The use of any one of claims 1-7, wherein the IFN- $\beta$  is not glycosylated.
  - 10. The use of claim 5, wherein the IFN- $\beta$  is IFN- $\beta$ -1a.
  - 11. The use of claim 5, wherein the IFN- $\beta$  is IFN- $\beta$ -1b.
  - 12. The use of any one of claims 1-11, wherein the IFN-β therapeutic comprises IFN-β fused to the constant domain of an immunoglobulin molecule.
- 25 13. The use of claim 12, wherein the immunoglobulin molecule is a human immunoglobulin molecule.
  - 14. The use of claim 13, wherein the immunoglobulin molecule is the heavy chain of IgG1.

- 15. The use of claim 14, wherein the IFN-β comprises SEQ ID NO: 14.
- 16. The use of any one of claims 1-15, wherein the IFN-β therapeutic comprises a pegylated IFN-β.
- The use of any one of claims 1-16, wherein the IFN-β therapeutic comprises a
   stabilizing agent.
  - 18. The use of claim 17, wherein the stabilizing agent is an acidic amino acid.
  - 19. The use of claim 18, wherein the stabilizing agent is arginine.
  - 20. The use of any one of claims 1-19, wherein the IFN-β therapeutic has a pH between about 4.0 and 7.2.
- 10 21. The use of any one of claims 1-20, wherein the IFN-β therapeutic is administered intravenously (i.v.).
  - 22. The use of any one of claims 1-20, wherein the IFN-β therapeutic is administered intra-muscularly (i.m.).
- The use of any one of claims 1-20, wherein the IFN-β therapeutic is administered
   subcutaneously.
  - 24. The use of any one of claims 1-23, wherein the treatment comprises administering several doses of the IFN-β therapeutic to the mammal.
  - 25. The use of claim 24, wherein the IFN-β therapeutic is administered weekly at a dose of about 6 MIU.
- 26. The use of claim 24, wherein the IFN-β therapeutic is administered three times a week at a dose of about 3 MIU.
  - 27. The use of any one of claims 1-26, wherein the treatment reduces proteinuria in the mammal.
- 28. The use of any one of claims 1-27, wherein the treatment reduces glomerular cell proliferation.
  - 29. The use of any one of claims 1-28, wherein the treatment reduces glomerular inflammation.
  - 30. The use of any one of claims 1-29, wherein the mammal is a human.

- 31. The use of claim 30, wherein the mammal is a mammal that is likely to develop glomerulonephritis as indicated by signs of an upcoming inflammation of at least one glomerulus.
- The use of any one of claims 1-31, wherein the mammal is not a mammal that
  harbors a virus causing glomerulonephritis or in which the glomerulonephritis was
  caused by a virus.
  - 33. The use of claim 32, wherein the mammal is not a mammal harboring a hepatitis virus or in which the glomerulonephritis was caused by a hepatitis virus.
- The use of claim 33, wherein the mammal is not a mammal harboring a hepatitis B or C virus or in which the glomerulonephritis was caused by a hepatitis B or C virus.
  - 35. The use of any one of claims 1-34, wherein the mammal does not have end-stage renal failure or renal cell carcinoma.
- 36. Use of an IFN-β therapeutic in the manufacture of a medicament for the treatment
   or prevention of chronic renal failure in a mammal.
  - 37. The use of claim 36, wherein the IFN-β therapeutic comprises mature IFN-β.
  - 38. The use of any one of claims 36-37, wherein the IFN-β therapeutic lacks the first methione.
  - 39. The use of any one of claims 36-38, wherein the IFN-β is human IFN-β.
- 20 40. The use of claim 39, wherein the IFN-β is at least about 95% identical to full length mature human IFN-β having SEQ ID NO: 4.
  - 41. The use of claim 40, wherein the IFN-β comprises SEQ ID NO: 4.
  - 42. The use of any one of claims 36-41, wherein the IFN-β is glycosylated.
    - 43. The use of any one of claims 36-41, wherein the IFN-β is not glycosylated.
- 25 44. The use of claim 39, wherein the IFN-β is IFN-β-1a.
  - 45. The use of claim 39, wherein the IFN- $\beta$  is IFN- $\beta$ -1b.
  - 46. The use of any one of claims 36-45, wherein the IFN-β therapeutic comprises IFN-β fused to the constant domain of an immunoglobulin molecule.

- 47. The use of claim 46, wherein the immunoglobulin molecule is a human immunoglobulin molecule.
- 48. The use of claim 47, wherein the immunoglobulin molecule is the heavy chain of IgG1.
- 5 49. The use of claim 48, wherein the IFN-β comprises SEQ ID NO: 14.
  - 50. The use of any one of claims 36-49, wherein the IFN-β therapeutic comprises a pegylated IFN-β.
  - 51. The use of any one of claims 36-50, wherein the IFN-β therapeutic comprises a stabilizing agent.
- 10 52. The use of claim 51, wherein the stabilizing agent is an acidic amino acid.
  - 53. The use of claim 52, wherein the stabilizing agent is arginine.
  - 54. The use of any one of claims 36-53, wherein the IFN-β therapeutic has a pH between about 4.0 and 7.2.
- 55. The use of any one of claims 36-54, wherein the IFN-β therapeutic is administered intravenously (i.v.).
  - 56. The use of any one of claims 36-54, wherein the IFN-β therapeutic is administered intra-muscularly (i.m.).
  - 57. The use of any one of claims 36-54, wherein the IFN- $\beta$  therapeutic is administered subcutaneously.
- 20 58. The use of any one of claims 36-57, wherein the treatment comprises administering several doses of the IFN-β therapeutic to the mammal.
  - 59. The use of claim 58, wherein the IFN-β therapeutic is administered weekly at a dose of about 6 MIU.
- The use of claim 58, wherein the IFN-β therapeutic is administered three times a
   week at a dose of about 3 MIU.
  - 61. The use of any one of claims 36-60, wherein the treatment reduces proteinuria in the mammal.
  - 62. The use of any one of claims 36-61, wherein the treatment reduces glomerular cell proliferation.

- 63. The use of any one of claims 36-62, wherein the treatment reduces glomerular inflammation.
- 64. The use of any one of claims 36-63, wherein the mammal is a human.
- 65. The use of claim 64, wherein the mammal is a mammal that is likely to develop chronic renal failure as indicated by chronic renal insufficiency.
  - 66. The use of any one of claims 36-65, wherein the mammal is not a mammal that harbors a virus causing chronic renal failure or in which the chronic renal failure was caused by a virus.
- The use of claim 66, wherein the mammal is not a mammal harboring a hepatitis virus or in which the chronic renal failure was caused by a hepatitis virus.
  - 68. The use of claim 67, wherein the mammal is not a mammal harboring a hepatitis B or C virus or in which the chronic renal failure was caused by a hepatitis B or C virus.
- The use of any one of claims 36-68, wherein the mammal does not have end-stage renal failure or renal cell carcinoma.
  - 70. A method for treating glomerulonephritis in a mammal, comprising identifying a mammal having glomerulonephritis and administering to the mammal a therapeutically effective amount of an IFN-β therapeutic.
- 71. The method of claim 70, wherein glomerulonephritis is selected from the group

  consisting of focal glomeruloscerosis, collapsing glomerulopathies, minimal change disease, crescentic glomerulonephritis, nephritic syndrome, nephrotic syndrome, primary glomerulonephritis, secondary glomerulonephritis, proliferative glomerulonephritis, membraneous glomerulonephritis, membranoproliferative glomerulonephritis, immune-complex glomerulonephritis, anti-glomerular basement membrane (anti-GBM) glomerulonephritis, pauci-immune glomerulonephritis, diabetic glomerulopathy, chronic glomerulonephritis, and hereditary nephritis.
  - 72. The method of claim 70 or 71, wherein the IFN- $\beta$  therapeutic comprises mature IFN- $\beta$ .
- 73. The method of any one of claims 70-72, wherein the IFN-β therapeutic lacks the
   30 first methione.

- 74. The method of any one of claims 70-73, wherein the IFN-β is human IFN-β.
- 75. The method of claim 74, wherein the IFN-β is at least about 95% identical to full length mature human IFN-β having SEQ ID NO: 4.
- 76. The method of claim 75, wherein the IFN-β comprises SEQ ID NO: 4.
- 5 77. The method of any one of claims 70-76, wherein the IFN- $\beta$  is glycosylated.
  - 78. The method of any one of claims 70-77, wherein the IFN-β is not glycosylated.
  - 79. The method of claim 74, wherein the IFN- $\beta$  is IFN- $\beta$ -1a.
  - 80. The method of claim 74, wherein the IFN- $\beta$  is IFN- $\beta$ -1b.
- The method of any one of claims 70-80, wherein the IFN-β therapeutic comprises
   IFN-β fused to the constant domain of an immunoglobulin molecule.
  - 82. The method of claim 81, wherein the immunoglobulin molecule is a human immunoglobulin molecule.
  - 83. The method of claim 82, wherein the immunoglobulin molecule is the heavy chain of IgG1.
- 15 84. The method of claim 83, wherein the IFN-β comprises SEQ ID NO: 14.
  - 85. The method of any one of claims 70-84, wherein the IFN-β therapeutic comprises a pegylated IFN-β.
  - 86. The method of any one of claims 70-85, wherein the IFN-β therapeutic comprises a stabilizing agent.
- 20 87. The method of claim 86, wherein the stabilizing agent is an acidic amino acid.
  - 88. The method of claim 87, wherein the stabilizing agent is arginine.
  - 89. The method of any one of claims 70-88, wherein the IFN-β therapeutic has a pH between about 4.0 and 7.2.
- The method of any one of claims 70-89, wherein the IFN-β therapeutic is
  administered intravenously (i.v.).
  - 91. The method of any one of claims 70-89, wherein the IFN-β therapeutic is administered intra-muscularly (i.m.).

- 92. The method of any one of claims 70-89, wherein the IFN-β therapeutic is administered subcutaneously.
- 93. The method of any one of claims 70-92, wherein the treatment comprises administering several doses of the IFN-β therapeutic to the mammal.
- 5 94. The method of claim 93, wherein the IFN-β therapeutic is administered weekly at a dose of about 6 MIU.
  - 95. The method of claim 93, wherein the IFN-β therapeutic is administered three times a week at a dose of about 3 MIU.
- 96. The method of any one of claims 70-95, wherein the treatment reduces proteinuria in the mammal.
  - 97. The method of any one of claims 70-96, wherein the treatment reduces glomerular cell proliferation.
  - 98. The method of any one of claims 70-97, wherein the treatment reduces glomerular inflammation.
- 15 99. The method of any one of claims 70-98, wherein the mammal is a human.
  - 100. The method of claim 99, wherein the mammal is a mammal that is identified as having glomerulonephritis by the presence of an inflammation of at least one glomerulus; glomerular hypertrophy; tubular hypertrophy; glomerulosclerosis; or tubulointerstitial sclerosis.
- 20 101. The method of any one of claims 70-100, wherein the mammal is not a mammal that harbors a virus causing glomerulonephritis or in which the glomerulonephritis was caused by a virus.
  - 102. The method of claim 101, wherein the mammal is not a mammal harboring a hepatitis virus or in which the glomerulonephritis was caused by a hepatitis virus.
- 25 103. The method of claim 102, wherein the mammal is not a mammal harboring a hepatitis B or C virus or in which the glomerulonephritis was caused by a hepatitis B or C virus.
  - 104. The method of any one of claims 70-103, wherein the mammal does not have end-stage renal failure or renal cell carcinoma.

- 105. A method for treating chronic renal failure in a mammal, comprising identifying a mammal having chronic renal failure and administering to the mammal a therapeutically effective amount of an IFN-β therapeutic.
- 106. The method of claim 105, wherein the IFN-β therapeutic comprises mature IFN-β.
- 5 107. The method of any one of claims 105-106, wherein the IFN-β therapeutic lacks the first methione.
  - 108. The method of any one of claims 105-107, wherein the IFN-β is human IFN-β.
  - 109. The method of claim 108, wherein the IFN-β is at least about 95% identical to full length mature human IFN-β having SEQ ID NO: 4.
- 10 110. The method of claim 109, wherein the IFN-β comprises SEQ ID NO: 4.
  - 111. The method of any one of claims 105-110, wherein the IFN-β is glycosylated.
  - 112. The method of any one of claims 105-110, wherein the IFN-β is not glycosylated.
  - 113. The method of claim 108, wherein the IFN-β is IFN-β-1a.
  - 114. The method of claim 108, wherein the IFN- $\beta$  is IFN- $\beta$ -1b.
- 15 115. The method of any one of claims 105-114, wherein the IFN-β therapeutic comprises IFN-β fused to the constant domain of an immunoglobulin molecule.
  - 116. The method of claim 115, wherein the immunoglobulin molecule is a human immunoglobulin molecule.
- 117. The method of claim 116, wherein the immunoglobulin molecule is the heavy chain of IgG1.
  - 118. The method of claim 117, wherein the IFN-β comprises SEQ ID NO: 14.
  - 119. The method of any one of claims 105-118, wherein the IFN-β therapeutic comprises a pegylated IFN-β.
- 120. The method of any one of claims 105-119, wherein the IFN-β therapeutic comprises a stabilizing agent.
  - 121. The method of claim 120, wherein the stabilizing agent is an acidic amino acid.
  - 122. The method of claim 121, wherein the stabilizing agent is arginine.

- 123. The use of any one of claims 105-122, wherein the IFN-β therapeutic has a pH between about 4.0 and 7.2.
- 124. The method of any one of claims 105-123, wherein the IFN-β therapeutic is administered intravenously (i.v.).
- 5 125. The use of any one of claims 105-123, wherein the IFN-β therapeutic is administered intra-muscularly (i.m.).
  - 126. The method of any one of claims 105-123, wherein the IFN- $\beta$  therapeutic is administered subcutaneously.
- 127. The use of any one of claims 105-126, comprising administering several doses of the IFN-β therapeutic to the mammal.
  - 128. The method of claim 127, wherein the IFN- $\beta$  therapeutic is administered weekly at a dose of about 6 MIU.
  - 129. The method of claim 127, wherein the IFN-β therapeutic is administered three times a week at a dose of about 3 MIU.
- 15 130. The method of any one of claims 105-129, wherein the treatment reduces proteinuria in the mammal.
  - 131. The method of any one of claims 105-130, wherein the treatment reduces glomerular cell proliferation.
- The method of any one of claims 105-131, wherein the treatment reduces glomerular inflammation.
  - 133. The method of any one of claims 105-132, wherein the mammal is a human.
  - 134. The method of claim 133, wherein the mammal is a mammal that is identified as having chronic renal failure by the presence of chronic renal insufficiency.
- The method of any one of claims 105-134, wherein the mammal is not a mammal that harbors a virus causing chronic renal failure or in which the chronic renal failure was caused by a virus.
  - 136. The method of claim 135, wherein the mammal is not a mammal harboring a hepatitis virus or in which the chronic renal failure was caused by a hepatitis virus.

- 137. The method of claim 136, wherein the mammal is not a mammal harboring a hepatitis B or C virus or in which the chronic renal failure was caused by a hepatitis B or C virus.
- 138. The method of any one of claims 105-137, wherein the mammal does not have endstage renal failure or renal cell carcinoma.

10

5

## This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

BLACK BORDERS

IMAGE CUT OFF AT TOP, BOTTOM OR SIDES

FADED TEXT OR DRAWING

BLURRED OR ILLEGIBLE TEXT OR DRAWING

SKEWED/SLANTED IMAGES

COLOR OR BLACK AND WHITE PHOTOGRAPHS

RAY SCALE DOCUMENTS

LINES OR MARKS ON ORIGINAL DOCUMENT

REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY

OTHER:

## IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.